Texas Administrative Code
Title 25. Health Services
Part 1. Department of State Health Services
Chapter 91. Cancer
Subchapter A. Cancer Registry
Effective Date: August 14, 2011

§91.1. Purpose.

This subchapter implements the Texas Cancer Incidence Reporting Act, Health and Safety Code, Chapter 82. This legislation concerns the reporting of cases of cancer for the recognition, prevention, cure or control of those diseases, and to facilitate participation in the national program of cancer registries established by 42 United States Code, §§280e - 280e-4. Nothing in this subchapter shall preempt the authority of facilities or individuals providing diagnostic or treatment services to patients with cancer to maintain their own cancer registries.

§91.2. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Cancer Incidence Reporting Act, Texas Health and Safety Code, Chapter 82.

(2) Branch--Cancer Epidemiology and Surveillance Branch of the ~~department~~Department.

(3) Cancer--Includes a large group of diseases characterized by uncontrolled growth and spread of abnormal cells; any condition of tumors having the properties of anaplasia, invasion, and metastasis; a cellular tumor the natural course of which is fatal, including intracranial and central nervous system malignant, borderline, and benign tumors as required by the national program of cancer registries; and malignant neoplasm, other than non-melanoma skin cancers such as basal and squamous cell carcinomas.

(4) Cancer Reporting Handbook--The branch's manual for cancer reporters that documents reporting procedures and format.

(5) Clinical laboratory--An accredited facility in which tests are performed identifying findings of anatomical changes; specimens are interpreted and pathological diagnoses are made.

(6) Department--Department of State Health Services.

(7) Health care facility--A general or special hospital as defined by the Health and Safety Code, Chapter 241; an ambulatory surgical center licensed under the Health and Safety Code,

Chapter 243; an institution licensed under the Health and Safety Code, Chapter 242; or any other facility, including an outpatient clinic, that provides diagnostic or treatment services to patients with cancer.

(8) Health care practitioner--A physician as defined by Occupations Code, §151.002 or a person who practices dentistry as described by the Occupations Code, §251.003.

(9) Personal cancer data--Information that includes items that may identify an individual.

(10) Quality assurance--Operational procedures by which the accuracy, completeness, and timeliness of the information reported to the ~~department~~ Department can be determined and verified.

(11) Report--Information provided to the ~~department~~ Department that notifies the appropriate authority of the occupancy of a specific cancer in a person, including all information required to be provided to the ~~department~~Department.

(12) Research--A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

(13) Statistical data--Aggregate presentation of individual records on cancer cases excluding patient identifying information.

(14) Texas Cancer Registry (TCR)--The cancer incidence reporting system administered by the Cancer Epidemiology and Surveillance Branch.

(15) Health Information Exchange (HIE) ~~--Refer to §182~~As defined by Section 182.151 of the Texas Health and Safety Code ~~for definition~~.

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http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.182.htm#182.151

§91.3. Who Reports and Access to Records.

(a) Each health care facility, clinical laboratory or health care practitioner shall report to the ~~department~~Department, by methods specified in §§91.4 - 91.7 of this title (relating to Cancer Registry), required data from each medical record pertaining to a case of cancer in its custody or under its control, except for cases to which subsection (d) of this section would apply.

(b) A health care facility or clinical laboratory providing screening, diagnostic or therapeutic services to patients with cancer shall grant the ~~department~~ Department or its authorized representative access to but not removal of all medical records which would identify cases of cancer, establish characteristics or treatment of cancer, or determine the medical status of any identified cancer patient.

(c) A health care practitioner providing diagnostic or treatment services to patients with cancer shall grant the ~~department~~ Department or its authorized representative access to but not removal of all medical records which would identify cases of cancer, establish characteristics or

treatment of cancer, or determine the medical status of any identified cancer patient except for cases to which subsection (d) of this section would apply.

(d) The ~~department~~ Department may not require a health care practitioner to furnish data or provide access to records if:

(1) the data or records pertain to cases reported by a health care facility providing screening, diagnostic, or therapeutic services to cancer patients that involve patients referred directly to or previously admitted to the facility; and

(2) the facility reported the same data the practitioner would be required to report.

(e) Health care facilities, clinical laboratories, and health care practitioners are subject to federal law known as the Health Insurance Portability and Accountability Act of 1996 found at Title 42 United States Code §1320d et seq.; the federal privacy rules adopted in Title 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164; and applicable state medical records privacy laws. Because state law requires reporting of cancer data, persons subject to this chapter are permitted to provide the data to the ~~department~~ Department without patient consent or authorization under 45 C.F.R. §164.512(a) relating to uses and disclosures required by law and §164.512(b)(1) relating to disclosures for public health activities. Both of these exceptions to patient consent or authorization are recognized in the state law.

§91.4. What to Report.

(a) Reportable conditions.

(1) The cases of cancer to be reported to the branch are as follows:

(A) all neoplasms with a behavior code of two or three in the most current edition currently in use in~~by~~ the U.S. of the International Classification on Diseases for Oncology (ICD-O) of the World Health Organization with the exception of those designated by the branch as non-reportable in the Cancer Reporting Handbook; and

(B) all benign and borderline intracranial and central nervous system neoplasms as required by the national program of cancer registries.

(2) Codes and taxa of the most current edition of the International Classification of Diseases, Clinical Modification of the World Health Organization which correspond to the branch's reportable list are specified in the Cancer Reporting Handbook.

(b) Reportable information.

(1) Except as provided in paragraph (2) of this subsection and health care practitioners in §91.5(c) of this title (relating to When to Report), those data required to be reported for each cancer case shall include ~~the patient's information on~~:

(A) patient name, address, zip code, and county of residence;

(B) patient social security number, date of birth, gender, race and ethnicity, marital status, birthplace, and primary payer at time of diagnosis, to the extent such information is available from the medical record;

(C) patient information on industrial and occupational history, smoking status, height and weight to the extent such information is available from the medical record;

(D) diagnostic information including the cancer site and laterality, cell type, tumor behavior, markers, grade and size, stage of disease, date of diagnosis, diagnostic confirmation method, sequence number, and other primary tumors;

(E) first course of cancer-related treatment, including dates and types of procedures;

(F) text information to support cancer diagnosis, stage and treatment codes;

(G) health care facility or practitioner related information including reporting institution number, casefinding source, type of reporting source, medical record number, registry number, tumor record number, class of case, date of first contact, date of last contact, vital status, facility referred from, facility referred to, managing physician, follow-up physician, date abstracted, abstractor, and electronic record version; and

(H) clinical laboratory related information including laboratory name and address, pathology case number, pathology report date, pathologist, and referring physician name and address.

(2) The ~~department~~ Department or its authorized representative may exempt a cancer reporter from providing specific reportable data items delineated in paragraph (1) of this subsection to the extent that those data to be exempted are not collected by the cancer reporter.

(3) Except as provided in §91.6(b) of this title (relating to How to Report), each report shall:

(A) be electronically readable and contain all data items required in paragraph (1) of this subsection;

(B) be fully coded and in a format prescribed by the branch;

(C) meet all quality assurance standards utilized by the branch;

(D) in the case of individuals who have more than one form of cancer, be submitted separately for each primary cancer diagnosed;

(E) be submitted to the branch electronically; and

(F) be transmitted and stored by secure means at all times to protect the confidentiality of the data.

§91.5. When to Report.

(a) All reports shall be submitted to the ~~department~~ Department within six months of the patient's admission, initial diagnosis, or treatment for cancer.

(b) Data shall be submitted no less than quarterly by health care facilities with annual caseloads of 400 or less. Monthly submissions are required for all other health care facilities.

(c) Data shall be submitted no less than quarterly by health care practitioners initially diagnosing a patient with cancer and performing the in-house pathological tests for that patient. Otherwise, data shall be submitted within 2 months of the request to a health care practitioner by the ~~department~~ Department or its authorized representative for a report or subset of a report on a patient diagnosed or treated elsewhere and for whom the same cancer data has not been reported.

(d) Data shall be submitted no less than quarterly by clinical laboratories.

§91.6. How to Report.

(a) Reports of cancer from health care facilities, clinical laboratories and health care practitioners shall be submitted to the branch electronically using ~~a~~ secure electronic processes ~~as defined~~specified by the ~~department~~Department and included on the Texas Cancer Registry website.

(1) Electronic reporting may occur through a Health Information Exchange by secure methods specified by the Department.

(b) The Texas Cancer Registry may accept the submission of paper copies of medical records from a health care facility, pathology reports from a clinical laboratory and reports or subsets of reports from a health care practitioner under the following conditions.

(1) The ~~department~~Department, or its authorized representative, shall determine that such paper submissions are more expedient than electronic reporting.

(2) The acceptance of paper submissions from a health care facility, clinical laboratory or health care practitioner shall be approved by the ~~department~~ Department or its authorized representative.

Commented [D(2]: Key section in which we need to add/change language to allow for HIE reporting.

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"…so this gives us flexibility over time without having to stop and amend the regulations every few years as technology or the national cancer registry standards change."

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(3) The ~~department~~Department, or its authorized representative, may approve acceptance of paper submissions from defined groups or types of health care facilities, clinical laboratories or health care practitioners.

(4) All records and reports provided to the Texas Cancer Registry pursuant to this subsection must be transmitted by secure ~~means at all times~~methods specified~~established~~ by the ~~d~~Department ~~to protect the confidentiality of the data~~.

§91.7. Where to Report.

Data reports should be submitted to the branch as specified in the Cancer Reporting Handbook and/or the Texas Cancer Registry website.

§91.8. Compliance.

(a) Each health care facility, clinical laboratory, or health care practitioner that successfully reports to the ~~department~~Department, by methods specified in §§91.4 - 91.7 of this title (relating to Cancer Registry), is considered compliant.

(b) A person will be notified in writing if the person has not reported in compliance with this chapter within 30 days following the end of the required monthly or quarterly reporting timeframe and will be given an opportunity to take corrective action within 60 days from the date of the notification letter. A second notification letter will be sent 30 days after the date of the original notification letter if no corrective action has been taken.

(c) If a person is non-compliant and takes no corrective action within 60 days of the original notification letter, the ~~department~~ Department or its authorized representative may access the information from the health care facility, clinical laboratory or health care practitioner as provided in §91.3 of this title (relating to Who Reports, Access to Records) and report it in the appropriate format.

(1) The health care facility, clinical laboratory or health care practitioner shall be notified at least two weeks in advance before a scheduled arrival for collection of the information.

(2) A health care facility, clinical laboratory or health care practitioner that knowingly or in bad faith fails to furnish data as required by this chapter shall reimburse the ~~department~~ Department or its authorized representative for its cost to access and report the information. The costs must be reasonable, based on the actual costs incurred by the ~~department~~ Department or by its authorized representative in the collection of the data and may include salary and travel expenses. It is presumed that a health care facility, clinical laboratory or health care practitioner acted knowingly or in bad faith if it failed to take corrective action within 60 days of the date of the original notification letter.

(3) A health care facility, clinical laboratory or health care practitioner may request the ~~department~~ Department to conduct a hearing under the ~~department's~~ Department's fair hearing rules to determine whether reimbursement to the ~~department~~ Department is appropriate.

(d) Any health care facility, clinical laboratory or health care practitioner which is required to reimburse the ~~department~~ Department or its authorized representative for the cost to access and report the information pursuant to subsection (c)(2) of this section shall provide payment to the ~~department~~ Department or its authorized representative within 60 days of the day this payment is demanded. In the event any health care facility, clinical laboratory or health care practitioner fails to make payment to the ~~department~~ Department or its authorized representative within 60 days of the day the payment is demanded, the ~~department~~ Department or its authorized representative may, at its discretion, assess a late fee not to exceed 1-1/2 % per month of the outstanding balance.

§91.9. Confidentiality and Disclosure.

(a) Pursuant to the Act, Chapter 82, §82.009, all data obtained is for the confidential use of the ~~department~~ Department and the persons or entities, public or private, that the ~~department~~ Department determines are necessary to carry out the intent of the Act.

(b) Limited release of the data is allowed by the Act, §82.008(h) and §82.009(b).

(c) Any requests for confidential or statistical data shall be made in accordance with §§91.11 or 91.12 of this title (relating to Cancer Registry).

(d) The Texas Cancer Registry is subject to state law that requires compliance with portions of the federal law and regulations cited in §91.3(e) of this title (relating to Who Reports, Access to Records). The ~~department~~ Department is authorized to use and disclose, for purposes described in the Act, cancer data without patient consent or authorization under 45 C.F.R §164.512(a) relating to uses and disclosures required by law, §164.512(b)(1) and (2) relating to uses and disclosures for public health activities, and §164.512(i) relating to uses and disclosures for research purposes.

§91.10. Quality Assurance.

The ~~department~~ Department shall cooperate and consult with persons required to comply with this chapter so that such persons may provide timely, complete, and accurate data. The ~~department~~ Department will provide:

(1) reporting training, technical assistance, on-site case-finding studies, and reabstracting studies;

(2) quality assessment reports to ascertain that the computerized data utilized for statistical information and data compilation is accurate; and

(3) educational information on cancer morbidity and mortality statistics available from the Texas Cancer Registry and the ~~department~~Department.

§91.11. Requests for Statistical Cancer Data**.**

(a) Statistical cancer data previously analyzed and printed are available upon written or oral request to the branch. All other requests for statistical data shall be in writing and directed to: Cancer Epidemiology and Surveillance Branch, Mail Code 1928, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347 or via email at CancerData@dshs.state.tx.us.

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(b) To ensure that the proper data are provided, the request shall include, but not be limited to, the following information:

(1) name, address, and telephone number of the person requesting the information;

(2) type of data needed and for what years (e.g. lung cancer incidence rates, Brewster County, 1998 - 2002); and

(3) name and address of person(s) to whom data and billings are to be sent (if applicable).

§91.12. Requests and Release of Personal Cancer Data.

(a) Data requests for research.

(1) Requests for personal cancer data shall be in writing and directed to: Department of State Health Services, Institutional Review Board (IRB), P.O. Box 149347, Austin, Texas 78714-9347.

(2) Written requests for personal data shall meet the submission requirements of the ~~department's~~ Department's IRB before release.

(3) The branch may release personal cancer data to state, federal, local, and other public agencies and organizations if approved by the IRB.

(4) The branch may release personal cancer data to private agencies, organizations, and associations if approved by the IRB.

(5) The branch may release personal cancer data to any other individual or entities for reasons deemed necessary by the ~~department~~ Department to carry out the intent of the Act if approved by the IRB.

(b) Data requests for non-research purposes.

(1) The branch may provide reports containing personal data back to the respective reporting entity from records previously submitted to the branch from each respective reporting entity for the purposes of case management and administrative studies. These reports will not be released to any other entity.

(2) The branch may release personal data to other areas of the ~~department~~Department, provided that the disclosure is required or authorized by law. All communications of this nature shall be clearly labeled "Confidential" and will follow established departmental internal protocols and procedures.

(3) The branch may release personal cancer data to state, federal, local, and other public agencies and organizations in accordance with subsection (a) of this section.

(4) The branch may release personal cancer data to any other individual or entities for reasons deemed necessary to carry out the intent of the Act and in accordance with subsection (a) of this section.

(5) An individual who submits a valid authorization for release of an individual cancer record shall have access to review or obtain copies of the information described in the authorization for release.